hiv/aids

4th Quarter '99

quarterly epidemiology report

Washington State ❍ Seattle & King County

Washington State/Seattle-King County HIV/AIDS Epidemiology Report

Summary Tables

HIV/AIDS Epidemiology and Surveillance News

To be included on the mailing list or to request address corrections, write to the PH-SKC HIV/AIDS Epidemiology Program or phone (206)296-4645, or email steve.hitchcock@metrokc.gov. We provide alternative formats for printed material upon request for people with special needs.

Credits

This is the fifty-fifth edition of a quarterly report on the epidemiology of HIV and AIDS. Produced as a joint project by Public Health-Seattle & King County and the Washington State Infectious Disease and Reproductive Health Assessment Unit, it is funded in part by a Centers for Disease Control and Prevention cooperative agreement for HIV/AIDS surveillance. We wish to thank the health care providers caring for people with HIV/AIDS and the clinics and patients participating in epidemiologic studies. Their cooperation with the public health departments' HIV/AIDS control efforts provides the basis for the data presented in this report. We also wish to acknowledge the outstanding assistance of our staff including Stephen Hitchcock, Jennifer Davis, Linda Oakley and Rusty Myers at Public Health-Seattle & King County, and Donna Compton, Mark Charonis, Tiffany Buckner, Anna Easton and Laraine Shann at the Washington State Infectious Disease and Reproductive Health Assessment Unit. Cover and document design by Stephen Hitchcock BA, BFA. Printed on recycled paper.

The HIV/AIDS Epidemiology Unit's publications are also on the internet at: www.metrokc.gov/health/apu

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HEALTHY PEOPLE. HEALTHY COMMUNITIES.

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HIV/AIDS Epidemiology Report becomes semiannual

The HIV/AIDS Epidemiology Report has been published quarterly since 1986. For the years 2000 and 2001, however, the Report will be reduced to a semiannual schedule. A mid-year issue with data through June will be released in August and a year-end issue will be released in February. This change is necessitated by the greatly increased workload experienced by the co-publishers of this report, the Washington Department of Health (DOH) and Public Health-Seattle & King County (PH-SKC), as we implement and evaluate a comprehensive system of HIV surveillance. Expanded laboratory reporting of HIV antibody and viral load test results is being implemented and thousands of previously-diagnosed persons with HIV will be reported over the next 2 years. Also, data reports are being redesigned to incorporate HIV case data. No new funding or staff is available to carry out this work. We appreciate your understanding during this time. For data users needing more frequent statistical updates, please contact PH-SKC or DOH to arrange to receive a monthly 2-page report of AIDS case data.

HIV/AIDS Reporting Requirements

Washington State implemented HIV infection reporting on September 1, 1999. Health care providers are required to report all HIV infections, regardless of the date of the patient's initial diagnosis to the local health department. However, the requirement is limited to those patients who seek care or are tested on or after September 1, 1999. Local health department officials will forward case reports to the State Department of Health, replacing the name of the patient with a standard code prior to forwarding if the report indicates asymptomatic infections. As has been the case since 1984, AIDS and symptomatic HIV case reports will not be subject to coding.

Laboratory evidence of HIV infection (i.e., western blot assays, p24 antigen detection, viral culture, nucleic acid detection [viral load]) also became reportable by laboratories effective September 1, 1999. Low CD4 counts (<200/µl or <14% of total lymphocytes) already have been reportable since 1993. However, laboratory reporting does not relieve health care providers of their duty to report since most of the critical information necessary for surveillance and follow-up is not available for reporting by laboratories.

Data collected through HIV infection reporting will be included in this report by late 2000. For further information about HIV/AIDS reporting requirements, please call your local health department or the Washington Department of Health at 1-888-367-5555. In King County contact the HIV/AIDS Epidemiology Program at 206-296-4645.

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Table 1. Surveillance summary of reported AIDS[1] cases, deaths, and persons living with AIDS - King County, other WA counties, all WA State, U.S.

		ADULT/ ADOLESCENT	PEDIATRIC[2]	TOTAL
KING COUNTY	*Cases reported as of 12/31/99*			
	New cases reported this quarter	47	0	47
	New cases reported year-to-date	210	0	210
	Cumulative cases	5,825	14	5,839
	Cumulative deaths	3,496	8	3,504
	Persons living[3]	2,329	6	2,335
OTHER COUNTIES	*Cases reported as of 12/31/99*			
	New cases reported this quarter	30	0	30
	New cases reported year-to-date	143	0	143
	Cumulative cases	3,071	17	3,088
	Cumulative deaths	1,726	10	1,736
	Persons living[3]	1,345	7	1,352
WA STATE	*Cases reported as of 12/31/99*			
	New cases reported this quarter	77	0	77
	New cases reported year-to-date	353	0	353
	Cumulative cases	8,896	31	8,927
	Cumulative deaths	5,222	18	5,240
	Persons living[3]	3,674	13	3,687
U.S.	*Cases reported as of 6/30/99*			
	Cumulative cases	702,748	8,596	711,344
	Cumulative deaths	415,190	5,011	420,201
	Persons living[3]	287,558	3,585	291,143

[1]AIDS by 1993 surveillance case definition
[2]Age < 13 years at time of AIDS diagnosis
[3]Persons reported with AIDS and not known to have died
[4]Most recent date that complete U.S. statistics are available

Table 2. Cumulative AIDS case counts and deaths by resident county and AIDSNet region at diagnosis - Reported as of 12/31/99 - WA State

		TOTAL CASES		DEATHS		PRESUMED LIVING	
		No.	(%)[1]	No.	(%)[2]	No.	(%)[2]
Region 1:	Adams	3	(0.0)	0	(0)	3	(100)
	Asotin	13	(0.1)	6	(46)	7	(54)
	Columbia	3	(0.0)	2	(67)	1	(33)
	Ferry	5	(0.1)	4	(80)	1	(20)
	Garfield	0	(0.0)	0	(0)	0	(0)
	Lincoln	2	(0.0)	2	(100)	0	(0)
	Okanogan	17	(0.2)	6	(35)	11	(65)
	Pend Oreille	8	(0.1)	4	(50)	4	(50)
	Spokane	349	(3.9)	204	(58)	145	(42)
	Stevens	14	(0.2)	6	(43)	8	(57)
	Walla Walla	48	(0.5)	26	(54)	22	(46)
	Whitman	7	(0.1)	4	(57)	3	(43)
	SUBTOTAL	**469**	**(5.3)**	**264**	**(56)**	**205**	**(44)**
Region 2:	Benton	60	(0.7)	28	(47)	32	(53)
	Chelan	30	(0.3)	19	(63)	11	(37)
	Douglas	2	(0.0)	2	(100)	0	(0)
	Franklin	18	(0.2)	9	(50)	9	(50)
	Grant	25	(0.3)	18	(72)	7	(28)
	Kittitas	13	(0.1)	7	(54)	6	(46)
	Yakima	118	(1.3)	65	(55)	53	(45)
	SUBTOTAL	**266**	**(3.0)**	**148**	**(56)**	**118**	**(44)**
Region 3:	Island	50	(0.6)	33	(66)	17	(34)
	San Juan	14	(0.2)	10	(71)	4	(29)
	Skagit	44	(0.5)	27	(61)	17	(39)
	Snohomish	465	(5.2)	259	(56)	206	(44)
	Whatcom	129	(1.4)	64	(50)	65	(50)
	SUBTOTAL	**702**	**(7.9)**	**393**	**(56)**	**309**	**(44)**
Region 4:	King	5,839	(65.4)	3504	(60)	2335	(40)
Region 5:	Kitsap	152	(1.7)	94	(62)	58	(38)
	Pierce	778	(8.7)	446	(57)	332	(43)
	SUBTOTAL	**930**	**(10.4)**	**540**	**(58)**	**390**	**(42)**
Region 6:	Clallam	40	(0.4)	19	(48)	21	(53)
	Clark	309	(3.5)	177	(57)	132	(43)
	Cowlitz	73	(0.8)	40	(55)	33	(45)
	Grays Harbor	37	(0.4)	20	(54)	17	(46)
	Jefferson	21	(0.2)	11	(52)	10	(48)
	Klickitat	10	(0.1)	8	(80)	2	(20)
	Lewis	33	(0.4)	23	(70)	10	(30)
	Mason	54	(0.6)	13	(24)	41	(76)
	Pacific	11	(0.1)	8	(73)	3	(27)
	Skamania	7	(0.1)	5	(71)	2	(29)
	Thurston	125	(1.4)	67	(54)	58	(46)
	Wahkiakum	1	(0.0)	0	(0)	1	(100)
	SUBTOTAL	**721**	**(8.1)**	**391**	**(54)**	**330**	**(46)**
TOTAL		**8,927**	**(100.0)**	**5,240**	**(59)**	**3,687**	**(41)**

[1] Percent of Washington State cases (column %)
[2] Percent of individual county's cases (row %)

Table 3. Demographic characteristics of cumulative reported AIDS[1] cases - King County, other WA counties, all WA State, U.S.

	KING COUNTY		OTHER COUNTIES		ALL WA STATE		TOTAL U.S.	
Cases reported as of:	12/31/99		12/31/99		12/31/99		6/30/99[2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
SEX								
Male	5,578	(96)	2,710	(88)	8,288	(93)	592,552	(83)
Female	261	(4)	378	(12)	639	(7)	118,789	(17)
Unknown	0	(0)	0	(0)	0	(0)	3	(<1)
AGE GROUP (YRS)								
< 13	14	(<1)	17	(1)	31	(<1)	8,596	(1)
13-19	10	(<1)	24	(1)	34	(<1)	3,564	(<1)
20-29	995	(17)	626	(20)	1,621	(18)	120,773	(17)
30-39	2,849	(49)	1,363	(44)	4,212	(47)	319,947	(45)
40-49	1,455	(25)	738	(24)	2,193	(25)	183,195	(26)
50-59	411	(7)	212	(7)	623	(7)	54,747	(8)
> 59	105	(2)	108	(3)	213	(2)	20,519	(3)
Unknown	0	(0)	0	(0)	0	(0)	3	(<1)
RACE/ETHNICITY								
White, not Hispanic	4,709	(81)	2,481	(80)	7,190	(81)	311,377	(44)
Black, not Hispanic	589	(10)	270	(9)	859	(10)	262,317	(37)
Hispanic	342	(6)	227	(7)	569	(6)	129,555	(18)
Asian/Pacific Islander	114	(2)	40	(1)	154	(2)	5,133	(1)
American Indian/AK Native	85	(1)	70	(2)	155	(2)	2,034	(<1)
Unknown	0	(0)	0	(0)	0	(0)	928	(<1)
HIV EXPOSURE CATEGORY								
Male-male sex	4,439	(76)	1,732	(56)	6,171	(69)	334,073	(47)
Injection drug use (IDU)	319	(5)	461	(15)	780	(9)	179,228	(25)
IDU & male-male sex	601	(10)	300	(10)	901	(10)	45,266	(6)
Heterosexual contact	181	(3)	270	(9)	451	(5)	70,582	(10)
Hemophilia	29	(<1)	55	(2)	84	(1)	5,243	(1)
Transfusion	53	(1)	65	(2)	118	(1)	8,806	(1)
Mother at risk/has HIV	13	(<1)	14	(<1)	27	(<1)	7,828	(1)
Undetermined/other[3]>	204	(3)	191	(6)	395	(4)	60,318	(8)
TOTAL CASES	**5,839**		**3,088**		**8,927**		**711,344**	

[1] AIDS by 1993 surveillance case definition
[2] Most recent date that complete U.S. statistics are available
[3] Includes patients for whom exposure information is incomplete (due to death, refusal to be interviewed, or loss to follow-up), patients still under investigation, patients whose only risk was heterosexual contact where the risk of the sexual partner was undetermined, persons exposed to HIV through their occupation, and patients whose mode of exposure remains undetermined

Table 4A. Cumulative AIDS[1] cases by gender, race/ethnicity, and HIV exposure category - Reported as of 12/31/99 - King County

EXPOSURE CATEGORY	WHITE[2] No.	(%)	BLACK[2] No.	(%)	HISPANIC No.	(%)	ASIAN/PI[3] No.	(%)	AI/AN[4] No.	(%)	TOTAL No.	(%)
MALE												
Male-male sex	3,768	(83)	301	(59)	240	(73)	88	(83)	42	(58)	4,439	(80)
Injection drug use (IDU)	130	(3)	73	(14)	31	(9)	3	(3)	7	(10)	244	(4)
IDU & male-male sex	499	(11)	52	(10)	27	(8)	4	(4)	19	(26)	601	(11)
Heterosexual contact	28	(1)	21	(4)	8	(2)	1	(1)	1	(1)	59	(1)
Hemophilia	27	(1)	1	(<1)	0	(0)	1	(1)	0	(0)	29	(1)
Transfusion	27	(1)	2	(<1)	2	(1)	1	(1)	1	(1)	33	(1)
Mother at risk/has HIV	3	(<1)	3	(1)	0	(0)	0	(0)	0	(0)	6	(<1)
Undetermined/other	80	(2)	56	(11)	20	(6)	8	(8)	3	(4)	167	(3)
MALE SUBTOTAL (row %)	**4,562**	**(82)**	**509**	**(9)**	**328**	**(6)**	**106**	**(2)**	**73**	**(1)**	**5,578**	**(100)**
FEMALE												
Injection drug use (IDU)	38	(26)	28	(35)	1	(7)	0	(0)	8	(67)	75	(29)
Heterosexual contact	77	(52)	30	(38)	9	(64)	3	(38)	3	(25)	122	(47)
Hemophilia	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)	0	(0)
Transfusion	13	(9)	5	(6)	1	(7)	1	(13)	0	(0)	20	(8)
Mother at risk/has HIV	3	(2)	2	(3)	2	(14)	0	(0)	0	(0)	7	(3)
Undetermined/other	16	(11)	15	(19)	1	(7)	4	(50)	1	(8)	37	(14)
FEMALE SUBTOTAL (row %)	**147**	**(56)**	**80**	**(31)**	**14**	**(5)**	**8**	**(3)**	**12**	**(5)**	**261**	**(100)**
TOTAL	**4,709**	**(81)**	**589**	**(10)**	**342**	**(6)**	**114**	**(2)**	**85**	**(1)**	**5,839**	**(100)**

Table 4B. Cumulative AIDS[1] cases by gender, race/ethnicity, and HIV exposure category - Reported as of 12/31/99 - WA State

EXPOSURE CATEGORY	WHITE[2] No.	(%)	BLACK[2] No.	(%)	HISPANIC No.	(%)	ASIAN/PI[3] No.	(%)	AI/AN[4] No.	(%)	TOTAL No.	(%)
MALE												
Male-male sex	5,266	(78)	399	(56)	330	(64)	108	(81)	68	(52)	6,171	(74)
Injection drug use (IDU)	369	(5)	120	(17)	69	(13)	4	(3)	21	(16)	583	(7)
IDU & male-male sex	751	(11)	70	(10)	44	(9)	4	(3)	32	(24)	901	(11)
Heterosexual contact	83	(1)	37	(5)	24	(5)	3	(2)	4	(3)	151	(2)
Hemophilia	78	(1)	1	(<1)	1	(<1)	1	(1)	0	(0)	81	(1)
Transfusion	60	(1)	3	(<1)	6	(1)	1	(1)	1	(1)	71	(1)
Mother at risk/has HIV	6	(<1)	5	(1)	0	(0)	0	(0)	1	(1)	12	(<1)
Undetermined/other	179	(3)	78	(11)	43	(8)	13	(10)	5	(4)	318	(4)
MALE SUBTOTAL (row %)	**6,792**	**(82)**	**713**	**(9)**	**517**	**(6)**	**134**	**(2)**	**132**	**(2)**	**8,288**	**(100)**
FEMALE												
Injection drug use (IDU)	118	(30)	55	(38)	7	(13)	2	(10)	15	(65)	197	(31)
Heterosexual contact	203	(51)	54	(37)	31	(60)	7	(35)	5	(22)	300	(47)
Hemophilia	3	(1)	0	(0)	0	(0)	0	(0)	0	(0)	3	(<1)
Transfusion	31	(8)	8	(5)	3	(6)	3	(15)	2	(9)	47	(7)
Mother at risk/has HIV	6	(2)	4	(3)	4	(8)	1	(5)	0	(0)	15	(2)
Undetermined/other	37	(9)	25	(17)	7	(13)	7	(35)	1	(4)	77	(12)
FEMALE SUBTOTAL (row %)	**398**	**(62)**	**146**	**(23)**	**52**	**(8)**	**20**	**(3)**	**23**	**(4)**	**639**	**(100)**
TOTAL	**7,190**	**(81)**	**859**	**(10)**	**569**	**(6)**	**154**	**(2)**	**155**	**(2)**	**8,927**	**(100)**

[1]AIDS by 1993 surveillance case definition
[2]And not Hispanic
[3]Asian/Pacific Islander
[4]American Indian/Alaska Native

Table 5. Cumulative AIDS[1] cases by gender and age at diagnosis Reported as of 12/31/99 - King County and WA State

	KING COUNTY				WASHINGTON STATE			
	MALE		FEMALE		MALE		FEMALE	
AGE (YRS)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
< 5	5	(<1)	5	(2)	11	(<1)	12	(2)
5-12	2	(<1)	2	(1)	5	(<1)	3	(<1)
13-19	7	(<1)	3	(1)	24	(<1)	10	(2)
20-29	922	(17)	73	(28)	1,461	(18)	160	(25)
30-39	2,737	(49)	112	(43)	3,948	(48)	264	(41)
40-49	1,415	(25)	40	(15)	2,072	(25)	121	(19)
50-59	395	(7)	16	(6)	579	(7)	44	(7)
> 59	95	(2)	10	(4)	188	(2)	25	(4)
TOTAL	**5,578**	**(100)**	**261**	**(100)**	**8,288**	**(100)**	**639**	**(100)**

[1] AIDS by 1993 surveillance case definition

Table 6. AIDS[1] cases, deaths, and case-fatality rates by year Reported as of 12/31/99 - King County and WA State

	KING COUNTY				WASHINGTON STATE		
YEAR OF DIAGNOSIS	CASES	(% TOTAL WA CASES)	DEATHS[2]	CASE-FATALITY RATE (%)[3]	CASES	DEATHS[2]	CASE-FATALITY RATE (%)[3]
1982	1	(100)	1	(100)	1	1	(100)
1983	11	(55)	11	(100)	20	20	(100)
1984	60	(76)	57	(95)	79	76	(96)
1985	104	(79)	100	(96)	131	127	(97)
1986	186	(75)	178	(96)	249	241	(97)
1987	274	(74)	261	(95)	370	352	(95)
1988	352	(71)	323	(92)	496	458	(92)
1989	461	(73)	415	(90)	628	562	(89)
1990	518	(69)	450	(87)	755	661	(88)
1991	561	(66)	464	(83)	853	709	(83)
1992	621	(67)	431	(69)	924	661	(72)
1993	643	(65)	372	(58)	994	595	(60)
1994	538	(61)	233	(43)	885	395	(45)
1995	503	(64)	116	(23)	784	197	(25)
1996	410	(59)	39	(10)	697	81	(12)
1997	285	(57)	33	(12)	504	58	(12)
1998[4]	221	(60)	17	(8)	370	33	(9)
1999[4]	90	(48)	3	(3)	187	13	(7)
TOTAL	**5,839**		**3,504**	**(60)**	**8,927**	**5,240**	**(59)**

[1]AIDS by 1993 surveillance case definition
[2]Number of deaths among persons diagnosed each year
[3]Percent of cases diagnosed in each year whose deaths have been reported to date
[4]Reporting for recent years is incomplete

Table 7A. AIDS cases by HIV exposure category and year of diagnosis Reported as of 12/31/99 - King County

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Male-male sex	354	(70)	282	(69)	179	(63)	139	(63)	57	(63)
Injection drug use (IDU)	47	(9)	35	(9)	14	(5)	22	(10)	7	(8)
IDU & male-male sex	46	(9)	31	(8)	32	(11)	22	(10)	11	(12)
Heterosexual contact	21	(4)	21	(5)	16	(6)	10	(5)	3	(3)
Hemophilia	1	(<1)	3	(1)	3	(1)	0	(0)	0	(0)
Transfusion	1	(<1)	0	(0)	3	(1)	3	(1)	1	(1)
Mother at risk/has HIV	1	(<1)	3	(1)	1	(<1)	0	(0)	0	(0)
Undetermined/other[3]	32	(6)	35	(9)	37	(13)	25	(11)	11	(12)

Table 7B. AIDS cases by HIV exposure category and year of diagnosis Reported as of 12/31/99 - Other Counties

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Male-male sex	134	(48)	142	(49)	99	(45)	65	(44)	32	(33)
Injection drug use (IDU)	54	(19)	49	(17)	38	(17)	31	(21)	28	(29)
IDU & male-male sex	19	(7)	28	(10)	16	(7)	11	(7)	6	(6)
Heterosexual contact	33	(12)	44	(15)	28	(13)	19	(13)	13	(13)
Hemophilia	6	(2)	2	(1)	4	(2)	0	(0)	1	(1)
Transfusion	6	(2)	4	(1)	4	(2)	1	(1)	1	(1)
Mother at risk/has HIV	3	(1)	1	(<1)	1	(<1)	0	(0)	0	(0)
Undetermined/other[3]	26	(9)	17	(6)	29	(13)	22	(15)	16	(16)

Table 7C. AIDS cases by HIV exposure category and year of diagnosis Reported as of 12/31/99 - WA State

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Male-male sex	488	(62)	424	(61)	278	(55)	204	(55)	89	(48)
Injection drug use (IDU)	101	(13)	84	(12)	52	(10)	53	(14)	35	(19)
IDU & male-male sex	65	(8)	59	(8)	48	(10)	33	(9)	17	(9)
Heterosexual contact	54	(7)	65	(9)	44	(9)	29	(8)	16	(9)
Hemophilia	7	(1)	5	(1)	7	(1)	0	(0)	1	(1)
Transfusion	7	(1)	4	(1)	7	(1)	4	(1)	2	(1)
Mother at risk/has HIV	4	(1)	4	(1)	2	(<1)	0	(0)	0	(0)
Undetermined/other[3]	58	(7)	52	(7)	66	(13)	47	(13)	27	(14)

[1]Reporting for recent years is incomplete
[2]Year to date (cases reported as of 12/31/99)
[3]Includes patients for whom exposure information is incomplete (due to death, refusal to be interviewed, or loss to follow-up), patients still under investigation, patients whose only risk was heterosexual contact where the risk of the sexual partner was undetermined, persons exposed to HIV through their occupation, and patients whose mode of exposure remains undetermined

Table 8A. AIDS cases by age/gender and year of diagnosis Reported as of 12/31/99 - King County

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Adult Male Cases	468	(93)	380	(93)	261	(92)	201	(91)	84	(93)
Adult Female Cases	34	(7)	27	(7)	23	(8)	20	(9)	6	(7)
Pediatric Cases	1	(<1)	3	(1)	1	(<1)	0	(0)	0	(0)

Table 8B. AIDS cases by age/gender and year of diagnosis Reported as of 12/31/99 - Other counties

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Adult Male Cases	229	(81)	235	(82)	182	(83)	130	(87)	72	(74)
Adult Female Cases	49	(17)	51	(18)	36	(16)	19	(13)	25	(26)
Pediatric Cases	3	(1)	1	(<1)	1	(<1)	0	(0)	0	(0)

Table 8C. AIDS cases by age/gender and year of diagnosis Reported as of 12/31/99 - WA State

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Adult Male Cases	697	(89)	615	(88)	443	(88)	331	(89)	156	(83)
Adult Female Cases	83	(11)	78	(11)	59	(12)	39	(11)	31	(17)
Pediatric Cases	4	(1)	4	(1)	2	(<1)	0	(0)	0	(0)

[1] Reporting for years is incomplete
[2] Year to date (cases reported as of 12/31/99)

Table 9. Deaths of reported AIDS cases by year of death Reported as of 12/31/99 - King County, Other counties, WA State

	1995		1996		1997		1998[1]		1999[1,2]	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
King County	450	(68)	284	(61)	104	(49)	88	(60)	39	(54)
Other Counties	215	(32)	178	(39)	108	(51)	59	(40)	33	(46)
All WA State	665	(100)	462	(100)	212	(100)	147	(100)	72	(100)

[1] Reporting for recent years is incomplete
[2] Year to date (deaths reported as of 12/31/99)

Table 10. Estimated number of persons living with AIDS at year's end King County, Other counties, WA State

	1996		1997[1]		1998[1]	
	No.	(%)	No.	(%)	No.	(%)
King County	2,027	(64)	2,251	(64)	2,406	(62)
Other Counties	1,142	(36)	1,290	(36)	1,468	(38)
All WA State	3,169	(100)	3,451	(100)	3,874	(100)

[1]AIDS cases numbers adjusted for reporting delay through 1998

New Guidelines for HIV and AIDS Case Surveillance

In December 1999, the federal Centers for Disease Control and Prevention (CDC) issued comprehensive guidelines for conducting the public health surveillance programs that monitor HIV and AIDS throughout the US and its territories. These guidelines, published in the Reports and Recommendation series of the *Morbidity and Mortality Weekly Report*, review the need for a national system of integrated HIV and AIDS surveillance, define adult and pediatric HIV infection, recommend surveillance program practices, and set performance and security standards for the conduct of these programs by local, state and territorial health departments.[1]

The goals of the expanded system of HIV/AIDS surveillance, as described by CDC, are to *"provide additional data about HIV-infected populations to enhance local, state, and federal efforts to prevent HIV transmission, improve allocation of resources for treatment services, and assist in evaluating the impact of public health interventions"*. The recommendations and the revised HIV case definition became effective on January 1, 2000 and their publication at this time was especially applicable to Washington State, with our recent implementation of HIV case reporting on September 1, 1999.

This article excerpts parts of the CDC report pertaining to the conduct of HIV/AIDS reporting and provides commentary from the local perspective. Due to space considerations, not all the references in the CDC report are included here. The CDC report also presents the history of HIV/AIDS surveillance in the US and describes the rationale behind the recommendation that all states and territories adopt HIV reporting as an extension of AIDS surveillance; some of this information was included in a previous issue of the Washington State/Seattle-King County *HIV/AIDS Epidemiology Report*[2] and therefore will not be covered here.

CDC's Recommended Surveillance Practices

The following recommendations were among those made by CDC. Excluded from the excerpt below are recommendations addressing standard and supplemental variables to be collected; surveillance for unusual HIV transmission routes or clinical presentations; data dissemination; and evaluation methods.

- On the basis of studies of coded identifier systems conducted in at least eight states, published evaluations of name-based and code-based surveillance systems, and CDC's assessment of the quality and reproducibility of the available data, CDC has concluded that confidential name-based HIV/AIDS surveillance systems are most likely to meet the necessary performance standards as well as to serve the public health purposes for which surveillance data are required. Therefore, CDC advises that state and local surveillance programs use the same confidential name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide. However, CDC recognizes that some states have adopted, and others may elect to adopt, coded case identifiers for public health reporting of HIV infection. CDC will provide technical assistance to all state and local areas to continue or establish HIV/AIDS surveillance systems and to evaluate their surveillance programs using standardized methods and criteria whether they use name or coded identifiers.

- HIV and AIDS case surveillance efforts should result in collection of data from all private and public sources of HIV-related testing and care services. Laboratory-initiated surveillance methods should identify all cases that meet the laboratory reporting criteria for HIV infection and/or AIDS. However, these methods will require follow-up with the provider to verify the infection status or clinical stage and obtain complete demographic and exposure risk data. HIV-infected persons who are initially tested anonymously are eligible to be reported to CDC's HIV/AIDS surveillance data-

base only after they have had HIV infection diagnosed in a confidential testing setting (e.g., by a health-care provider) and have test results or clinical conditions that meet the HIV and/or AIDS reporting criteria.

COMMENTARY: *One of the most contentious issues addressed in the CDC report on HIV surveillance was that of HIV reporting by confidential name-based or code-based methods. After several years of consideration, CDC concluded that name-based systems are the most likely to meet the necessary performance standards (see next section) while recognizing that named reporting is not feasible in all states. In implementing HIV reporting last year, Washington State took a novel approach: name-based reporting with subsequent encoding and elimination of the name on HIV reports. This method was derived by a consensus approach, balancing the concerns of public health for a system likely to meet CDC performance standards while controlling the burden on reporting physicians and laboratories (who do not have to formulate and track a coded identifier) and fostering the cooperation of HIV/AIDS-affected communities in the state concerned about assuring confidentiality of case records. Other states including Maine, Montana, and Oregon have since adopted or are considering similar systems.*

With technical assistance from CDC, the surveillance programs of the Washington Department of Health and Public Health—Seattle & King County are actively evaluating this approach to HIV surveillance. A report will be compiled by DOH and presented to the State Board of Health in the fall of 2000. At this time, evaluation data will also be shared with CDC in preparation for initiating transfer of Washington State HIV case data to CDC. Assuming satisfactory data quality, HIV reporting data from Washington will be included in the CDC's year-end 2000 data reports.

In implementing HIV infection reporting, the Washington State Board of Health recognized the importance of laboratory reporting of test results indicative of HIV infection. Beginning 9/1/99, laboratories serving providers in Washington State are required to report to public health confirmed HIV positive antibody tests, detectable HIV viral load results, and CD4 + T-lymphocyte tests < 200 or 14% (indicating AIDS). Since 1993, when the case definition of AIDS was expanded to include immunologic criteria of low CD4 counts, laboratory reporting of CD4 test results has been responsible for initiating about 40% of AIDS case reports in Washington State. All laboratory reports are followed up with providers to verify the test results and obtain a complete case report. It is anticipated that laboratory reporting of HIV test results will be equally critical in assuring complete case reporting. As recommended by CDC, results of anonymous HIV tests are not reportable in Washington until the patients enter confidential care systems.

CDC's Minimum Performance Standards for HIV/AIDS Surveillance

- To provide accurate and timely data for monitoring HIV/AIDS trends and ensuring a reliable measure of the number of persons in need of HIV-related prevention and care services, state and local HIV/AIDS surveillance systems should use reporting methods that provide case reporting that is complete (greater than or equal to 85%) and timely (greater than or equal to 66% of cases reported within 6 months of diagnosis). In addition, evaluation studies should demonstrate that the approach used to conduct surveillance (i.e., name or coded identifier) must result in accurate case counts (less than or equal to 5% duplicate case reports and less than or equal to 5% incorrectly matched case reports). Finally, at least 85% of reported cases or a representative sample should have information regarding risk for HIV infection after epidemiologic follow-up is completed. All HIV/AIDS surveillance systems should collect the recommended standard data in a reliable and valid manner, allow matching to other public health databases (e.g., death registries) to benefit specific public health goals, and allow identification and follow-up of individual cases of public health importance.

- To assess the quality of HIV and AIDS case surveillance as specified in the performance standards, states and local surveillance programs must conduct periodic evaluation studies. CDC will recommend several evaluation methods to enable states to select methods best suited to their program needs and resources. States should also evaluate the representativeness of their HIV case reports by

monitoring the potential impact of HIV surveillance on test-seeking patterns and behaviors and review the extent to which surveillance data are being used for planning, targeting, and evaluating HIV-prevention programs and services. The goal of these performance evaluations is to enhance the quality and usefulness of surveillance data for public health action. During the next several years (i.e., 2000-2002), CDC will assist states in transitioning to an integrated HIV/AIDS surveillance system by evaluating current performance levels, instituting revised program operations and policies as necessary, and then reassessing performance. Following this transition period, CDC will evaluate and award proposals for federal funding of state and local surveillance programs based on their capacity to meet these performance standards. At that time, CDC will require that recipients of federal funds for HIV/AIDS case surveillance adopt surveillance methods and practices that will enable them to achieve the standards to ensure that federal funds are awarded responsibly.

***COMMENTARY**: The Washington Department of Health and Public Health—Seattle & King County are working to evaluate the performance of HIV/AIDS surveillance in this state in accordance with the CDC guidelines and specific mandates from the State Board of Health. Evaluations of AIDS surveillance in Washington conducted over the past several years indicate that AIDS reporting has been 90-95% complete, substantially exceeding the minimum standard of 85%. Analysis of the timeliness of AIDS reporting in the period 7/98 – 6/99 indicated that 63% of Washington's AIDS cases were reported within 6 months of diagnosis, falling somewhat short of the CDC's minimum standard of 66%. This is likely related to the quarterly reporting of CD4 counts by laboratories during this period. Beginning 9/1/99, laboratories are required to report monthly instead of quarterly and this should reduce delays in follow-up of lab-initiated reports. Estimation of the duplication and incorrect case matching rates within the Washington State AIDS registry has not been done in recent years. These estimates are part of the current evaluation study of the performance of the non-name coded identifiers that has been adopted for HIV reporting in Washington State.*

For AIDS cases in Washington, about 15% of case reports are received without indication of the risk factor for HIV transmission. Active epidemiologic follow up by surveillance staff resolves some of these cases such that 90-93% of cases are eventually classified as to HIV risk, exceeding the 85% level in CDC's guidance. Unfortunately, there have been no increases in public health funding or staffing commensurate with the greatly increased volume of cases generated by HIV reporting. Accordingly, the surveillance programs in Washington State will prioritize cases among women and children and those cases potentially exposed through receipt of blood products for epidemiologic follow-up when these cases are initially reported with no identified risk.

The representativeness of cases and any adverse impact of the new HIV reporting requirements will be evaluated by surveys of persons at risk for HIV. Public Health—Seattle & King County has received funding from CDC to conduct the HITS-2000 survey of 300 persons in King County (100 gay men; 100 injection drug users, and 100 heterosexuals attending sexually-transmitted disease clinics) to determine knowledge and attitudes about HIV surveillance and influence on HIV testing and care-seeking behaviors. These data will be used locally as well as combined with data collected in 7 other cities or states funded under HITS-2000. The Washington Department of Health has applied for other funding to conduct similar surveys in other areas of the state.

CDC's Minimum Security and Confidentiality Practices

 The security and confidentiality policies and procedures of state and local surveillance programs should be consistent with CDC standards for the security of HIV/AIDS surveillance data.[3,4] The minimum security criteria were established following reviews of all state and numerous local health department HIV/AIDS surveillance programs. In general, the reviews documented that health departments have achieved a high level of security and that most state health departments meet or exceed the minimum standards. Beginning in 2000, CDC will require that recipients of federal funds for HIV/AIDS surveillance establish the minimum security standards and include their security policy in applications for surveillance funds.[3,4] Examples of these standards include the following:

–Electronic HIV/AIDS surveillance data should

be protected by computer encryption during data transfer. States should continue the established practice of not including personal identifying information in HIV/AIDS surveillance data forwarded to CDC.

–HIV and AIDS surveillance records should be located in a physically secured area and should be protected by coded passwords and computer encryption.

–Access to the HIV/AIDS surveillance registry should be restricted to a minimum number of authorized surveillance staff, who are designated by a responsible authorizing official, have been trained in confidentiality procedures, and are aware of penalties for unauthorized disclosure of surveillance information.

–Public health programs that receive HIV/AIDS information from matching of public health databases should have security and confidentiality protections and penalties for unauthorized disclosure equivalent to those for HIV/AIDS surveillance data and personnel.

–Use of HIV/AIDS surveillance data for research purposes should be approved by appropriate institutional review boards, and persons conducting the research must sign confidentiality statements.

–HIV and AIDS surveillance data made available for epidemiologic analyses must not include names or other identifying information. State and local data release policies should ensure that the release of data for statistical purposes does not result in the direct or indirect identification of persons reported with HIV infection and AIDS.

–In the rare instance of a possible security breach of HIV/AIDS surveillance data, state and local health departments should promptly investigate and report confirmed breaches to CDC to enable CDC to provide technical assistance to state and local health departments, develop recommendations for improvements in security measures, and provide oversight in monitoring changes in program practices.

COMMENTARY: *The Washington Department of Health (DOH) and Public Health—Seattle & King County (DOH's subcontractor for HIV/AIDS surveillance activities in King County) have a strong program for maintaining the security and confidentiality of surveillance data. The CDC minimum standards are met or exceeded by the two programs, and DOH provides on-going training and technical assistance to other local health jurisdictions in the state which collect HIV/AIDS case data. With the institution of HIV reporting, DOH undertook to have each jurisdiction name an "Overall Responsible Party" to assure local compliance with DOH and CDC security and confidentiality standards and to assure that names of persons reported with asymptomatic HIV infection are encoded within 90 days of completion of the case report.*

With the development of the HIV reporting laws, public health and community advocacy groups sought to strengthen the protection of HIV data. This was accomplished by state legislation which increased the penalties for reckless or intentional disclosure of HIV status by public health staff, health care providers or other persons involved in disease reporting to $10,000 or actual damages, whichever is greater. Another provision of the legislation was that any incidents of unauthorized disclosure by DOH, local health departments or their employees must be reported annually to the State Board of Health, along with recommendations for preventing future unauthorized disclosures and improving the system of confidentiality for reported information. Washington Administrative Code also requires that state and local health officers investigate potential breaches of confidentiality of HIV identifying information by health department employees and that all breaches be reported to the state health officer for review and appropriate action.

Relation to HIV-Prevention and HIV-Care Programs: Recommended Practices

 At the federal level, the primary function of HIV/AIDS surveillance is collecting accurate and timely epidemiologic data for public health planning and policy. Consequently, CDC is authorized to provide federal funds to states through surveillance cooperative agreements, both to achieve the goals of the national surveillance program and to assist states in developing their surveillance programs in accordance with state and local laws and practices. Federal funds authorized for HIV/AIDS surveillance are not provided to states for developing or providing prevention or treatment case-management services; funds for such services are provided by CDC and other federal agencies under separate authorizations.

 Whether and how states establish a link between individual case-patients reported to

their HIV/AIDS surveillance programs and other health department programs and services for HIV prevention and treatment is within the purview of the states. However, in considering or establishing such linkages, CDC recommends the following:

–The implementation of HIV case surveillance should not interfere with HIV- prevention programs, including those that offer anonymous HIV counseling and testing services. Unless prohibited by state law or regulation, as a condition of federal funding for HIV prevention under a separate authorization, CDC requires that states and local areas provide anonymous HIV counseling and testing services. CDC strongly recommends that states which prohibit anonymous HIV testing change this practice, given the overriding public health objective of encouraging persons to become aware of their HIV serologic status. CDC does not view the availability of publicly funded anonymous counseling and HIV testing as incompatible with the ability to conduct HIV case surveillance in the population.

–HIV testing services should be offered for participation on a voluntary basis and preceded by informed consent in accordance with local laws.[5]

–Both public and private providers should refer persons in whom HIV infection has been diagnosed to programs that provide HIV care, treatment, and comprehensive prevention case-management services.

–Provider-based referrals of patients to prevention and care services should enable a timely, effective, and efficient means of ensuring that persons in whom HIV infection has been diagnosed receive needed services.

–States should consult with providers, prevention- and care-planning bodies, and public health professionals in developing the policies and practices necessary to effect these linkages; should require that recipients of HIV/AIDS surveillance information be subject to the same penalties for unauthorized disclosure as HIV/AIDS surveillance personnel; and should evaluate the effectiveness of this public health approach. Such an evaluation should ensure that the public health objectives of such linkages are achieved without unnecessarily increasing security and confidentiality risks to surveillance data or decreasing the acceptability of surveillance programs to health-care providers and affected communities. Providers and affected communities, including HIV-prevention community planning groups, should participate with health departments in planning and implementing surveillance strategies, as well as programs and services.

COMMENTARY: *In writing the HIV reporting rules for Washington State, public health officials were careful to support the continuing availability of anonymous testing for HIV and to allow any person authorized to conduct HIV testing to provide this service anonymously. Furthermore, the law requires that persons considering confidential testing must be informed of the availability of anonymous testing, the differences between anonymous and confidential testing, and that, if tested confidentially, persons testing HIV positive will be reported by name to the state or local public health officer. Persons testing HIV positive by anonymous testing are not reported to public health until such time as they receive health care services.*

Patient counseling and referral services (PCRS), formerly known as partner notification, is an HIV prevention tool that is linked to HIV/AIDS reporting in many states. In Washington State, administrative code (WAC 246-100-072) requires that the health care provider diagnosing HIV infection assure PCRS. Most often the patients themselves agree to inform sexual and needle-sharing partners of their exposure to HIV. However, patient follow through and prevention effectiveness of patient- and provider-based PCRS remain to be implemented and evaluated. The lengthy process of formulating the administrative rules for HIV surveillance and related issues in Washington included many opportunities for input from providers and the affected community. Accordingly, while public health is available to assist in PCRS, the WACs were careful to state that local health officers must not contact the HIV-infected person directly without considering the recommendation of the principal health care provider on the necessity and best means for conducting case follow-up.

To augment HIV prevention, the HIV/AIDS case report form developed in Washington State contains fields to remind and assist health care providers in their duty to assure notification of the sexual and needle sharing partners and the current or former (within 10 years) spouses of persons testing HIV positive. The first field is for patient's marital status. The health care provider of a patient indicated as being currently or formerly married receives a reminder from the health department of the federal require-

ment for spousal notification of HIV exposure. Second, a field in the Treatment/Services Referral section asks providers to indicate, for patients diagnosed after 9/1/99, whether the provider assumes responsibility for ensuring partner notification or whether the provider would like a call from their local health department for assistance in discussing and/or conducting partner notification. In the first 6 months of HIV reporting, only two providers practicing in King County have requested health department assistance in partner notification whereas about one-third of the nearly 200 case reports submitted by providers in the remainder of the state have asked for this consultation.

For more information about the CDC guidelines for HIV/AIDS surveillance, the full text of the report with the complete listing of 127 references is available on-line at the CDC website at http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4813a1.htm. For a printed copy, write to the Superintendent of Documents, US Government Printing Office, Washington DC 20402 or call (202)512-1800.

Questions about HIV/AIDS reporting in Seattle-King County should be addressed to Dr. Sharon Hopkins at (206)296-4645 or e-mail at sharon.hopkins@metrokc.gov. Outside King County, contact the local health officer or Dr. Chris Spitters at the Washington Department of Health at (360)236-3455.

❑ *Contributed by Sharon G. Hopkins DVM, MPH with thanks to Dr. Chris Spitters for his review and editorial comments.*

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[2]Hopkins S, Spitters C, Jourden J, Peppert J. HIV Reporting in Washington State: Questions and Answers. **HIV/AIDS Quarterly Epidemiology Report** 1999, 2nd Quarter.

[3]CDC. Guidelines for HIV/AIDS surveillance. Atlanta, GA: US Department of Health and Human Services, Public Health Service, 1996.

[4]CDC. Update: guidelines for HIV/AIDS surveillance — Appendix C: security and confidentiality. Atlanta, GA: US Department of Health and Human Services, 1998.

[5]CDC. Public Health Service guidelines for counseling and antibody testing to prevent HIV infection and AIDS. **MMWR** 1987;36:509-15.

Racial and Ethnicity Classification of Persons with HIV/AIDS in Washington State: a comparison of two public health databases

Collection of race and ethnicity information is an important component of any public health surveillance system used to address differences in health status among population subgroups. The ability to understand the differential distribution of health problems among racial/ethnic groups is needed to develop and direct effective programs and services.

As in many parts of the United States, people from certain racial/ethnic backgrounds in Washington State continue to be overrepresented in the HIV epidemic. Accurate reporting of race and ethnicity is necessary to assess the impact of HIV on these population groups in order to better allocate resources for prevention and care services. However, there are many challenges inherent in collecting and interpreting data on race and ethnicity, including differences in data collection procedures, differences in question content and format, and differences in perceptions of group identity. In this article, a comparison of race/ethnicity classifications of persons with symptomatic HIV and AIDS from two reporting sources (AIDS case reports and self-reported interview data) will be presented, as well as a discussion of some of the challenges of collecting and interpreting race and ethnicity data.

Methods

HIV/AIDS Reporting System: In Washington State, symptomatic HIV and AIDS cases have been reported by health care providers to state or local health departments since 1987 using a uniform case report form. Information from these confidential case report forms, which includes demographic characteristics, HIV exposure risks, and diseases indicative of symptomatic HIV/AIDS, is recorded in HARS (HIV/AIDS Reporting System). Race and Hispanic ethnicity are collected as a single variable with mutually exclusive categories: white (not Hispanic), black (not Hispanic), Hispanic, Asian/Pacific Islander, American Indian/Alaska native, and not specified. Information is typically obtained from medical records or via provider report and not from personal interview.

Interview (Self-reported) Data (SHAS): Self-reported race and ethnicity information is collected as part of the Supplement to HIV/AIDS Surveillance (SHAS) Interview Project. In this project, persons 18 years and older reported with symptomatic HIV and AIDS are interviewed to obtain more detailed information on socioeconomic status, sexual behaviors, drug and alcohol use, use of health services, reproductive health, and preventive therapy use. Additional description of the SHAS project can be found in previous *HIV/AIDS Epidemiology Reports* (Q3, 1991; Q1, 1999). A total of 1,427 interviews conducted between 1991 and 1999 were included in this analysis.

The SHAS questionnaire includes two questions on race and ethnicity:

(1) "Do you consider yourself to be Hispanic or Latino?" Answers were yes or no.

(2) **"What racial group do you consider yourself to be?"** Answers were classified as follows: white, black, American Indian, Alaskan native, Asian or Pacific Islander, multi-racial (added in 1995), other, unknown.

For this analysis, race and Hispanic ethnicity questions, coded as two independent variables on the interview, were recoded to create a single variable comparable with race/ethnicity categories on the AIDS case report form (white, not Hispanic; black, not Hispanic; Hispanic; Asian/Pacific Islander; or American Indian/Alaska native.) All persons answering "yes" to Hispanic or Latino ethnicity were coded as "Hispanic", regardless of race specified. American Indian and Alaska native categories were collapsed together. Self-reported race/ethnicity from SHAS was compared with race/ethnicity on the AIDS case report in HARS of the same individual.

Table 1. Percent agreement of race/ethnicity between SHAS interviews and case reports for adults reported with symptomatic HIV/AIDS

	Self-reported Race/Ethnicity (SHAS)					
AIDS Case Report	White n = 1026 (%)	Black n = 156 (%)	Hispanic n = 139 (%)	Asian/PI n = 21 (%)	AI/AN n = 41 (%)	Other n = 44 (%)
White	98.5	3.3	18.0	9.5	26.8	54.5
Black	0.1	94.8	5.1	0.0	4.9	34.1
Hispanic	0.4	0.0	74.8	9.5	2.4	6.8
Asian/PI	0.3	1.3	0.7	81.0	2.4	4.5
AI/AN	0.6	0.6	0.7	0.0	63.4	0.0
Unknown	0.1	0.0	0.7	0.0	0.0	0.0
Total	100	100	100	100	100	100

Results

In Table 1, reporting of race/ethnicity based on interviews is compared with reporting on AIDS case reports. Agreement was highest for whites (99%) and blacks (95%). For other groups, agreement between self-reported race/ethnicity and that collected on AIDS case reports was lower. Agreement was lowest among American Indians/Alaska natives; 15 of 41 persons who self-reported as American Indian/Alaska native during interview were classified in other race/ethnicity categories on the AIDS case report form, in most cases the "white" category. This misclassification was also seen among persons who self-reported as Hispanic; most of those misclassified on the AIDS case report form were misclassified as white.

Discussion

A comparison of the classification of race and ethnicity in AIDS case reports with information obtained from SHAS interviews indicated that these sources were highly consistent for whites and blacks, but less consistent for Hispanics, American Indians/Alaskan natives, and Asian/Pacific Islanders. These findings indicate that current surveillance methods underestimate the impact of the HIV/AIDS epidemic in these communities. American Indians/Alaskan natives were most likely to be misclassified; these results are consistent with results from a study done of racial ascertainment of American Indians/Alaskan natives in Seattle-King County in which only one of six persons with AIDS who self-identified as American Indian/Alaskan native had been identified as such on the AIDS case report.[1] They are also consistent with results of a similar analysis done using HARS and SHAS data from all SHAS study sites.[2]

Data on race and ethnicity that are routinely used to examine the health status of different subpopulations may be imprecise for a variety of reasons. Different methods of data collection may yield different results. In the case of this comparison, HIV/AIDS surveillance data were collected primarily by health care providers from information contained in medical records. This information may differ from individuals' self-perception of race/ethnicity, which is the information captured on the SHAS interview. According to Bureau of Census evaluations, self-identification results in more consistent reporting of race/ethnicity than an enumerator's observation.[3]

Even when data are self-reported, misclassification may still occur. Persons with HIV/AIDS may provide misinformation on race or ethnicity to avoid discrimination or protect confidentiality. A 1998 needs assessment of Native Americans indicated that one reason that epidemiologic and surveillance data are not used by HIV prevention programs is the perceived level of misclassification, by both health care providers and clients, in the data.[4] Additionally, misclassification may occur be-

cause individuals may have different interpretations of racial/ethnic categories, so may respond to questions about race/ethnicity in a variety of ways.

Differences in how questions are asked about race and ethnicity may also result in variations in classification. The HIV/AIDS case report form contains a single question about race/Hispanic ethnicity, while the SHAS interview contains two independent questions about Hispanic ethnicity and race.

There are many complexities associated with collecting and analyzing data on race and ethnicity; nonetheless, these classifications will continue to be used as surrogates for economic, cultural, and social determinants of health. While it would be desirable to collect more in-depth information on socioeconomic status in all health data sets, time and resources are often not available to do so. However, it will be important to periodically evaluate socioeconomic measures that are associated with health disparities between population groups in order to improve interpretation of racial/ethnic disparities in HIV/AIDS rates. Better understanding of the meaning of race and ethnicity, as well as what it means to the respondents providing the information, will allow for appropriate use of the information to better target HIV prevention and care services.

Washington State continues to become a more racially and ethnically diverse place. The Office of Management and Budget issued a revised standard for reporting of race and ethnicity that will be used in the U.S. Census in 2000 and in birth and death certificates by 2003, and will most likely be adopted by other data collection systems over time. The biggest impact of the revisions is the ability of respondents to select multiple racial categories - since a growing proportion of the population is multiracial, this information is necessary to accurately characterize the population and its diversity. A description of the revisions and guidelines for data analyses are located at www.doh.wa.gov/data/guidelines/guidelines.htm.

❑ *Contributed by Maria Courogen MPH*

[1] Hurlich MG, Hopkins SG, Sakuma J, and Conway GA. Racial ascertainment of American Indian/Alaska natvie persons with AIDS – Seattle/King County, WA 1980-1989. **The IHS Primary Care Provider** 1992: 73-74.

[2] Kelly JJ, Chu SY, Diaz T, Leary LS, Buehler JW et al. Race/ethnicity misclassification of persons reported with AIDS. **Ethnicity and Health** 1996; 1(1): 87-94.

[3] McKenney NR and Bennett CE. Issues regarding data on race and ethnicity: The Census Bureau experience. **Public Health Reports** 1994; 109(1): 16-25.

[4] Intertribal Council of Arizona, Northwest Portland Area Indian Health Board, and National Native American AIDS Prevention Center. **National Native HIV/AIDS Prevention Needs Assessment 1998**.

SHAS staff would like to thank all of the hundreds of men and women living with reportable HIV for their willingness to share their experiences, and the many health care providers and case managers whose assistance in recruiting patients to participate has made this project possible.

HIV Prevalence among Military Recruit Applicants in Seattle, Tacoma, and Washington State

Since October 1985, all persons applying for active or reserve military service, the service academies or the Reserve Officer Training Corps have been screened for HIV infection as part of their entrance medical evaluation. The Department of Defense shares these data with the Centers for Disease Control and Prevention (CDC) for HIV surveillance purposes. The CDC compiles the data and issues periodic reports to state and local health departments.[1]

Until mid-1993, all applicants were interviewed prior to medical evaluation about drug use and male-male sexual activity (both of which have been grounds for exclusion from entry into military service). On July 19, 1993, President Clinton authorized a new policy in which military applicants are not asked about homosexual activity, aka "*don't ask, don't tell*". Potential applicants are informed that they will be screened for HIV antibody. Thus, despite the new policy about homosexual behavior, it is expected that men who have sex with men, injection drug users, and others with known risk factors are underrepresented among military applicants who are medically evaluated.

Between 10/85 and 12/98, 5,789,751 persons nationwide were tested in this program. Of these, 70% were White, 19% Black, 7% Hispanic, and 4% of other races.

Table 1 shows cumulative national rates of persons testing HIV positive compared with those for Washington, Seattle (King, Snohomish, and Island counties) and Tacoma (all of Pierce County) Metropolitan Statistical Areas (MSA).

Examination of these data reveal:

- Washington state's HIV seropositivity rate was less than half that of the nation as a whole: 0.03% versus 0.08%.

- The percent of Washington recruits testing HIV positive dropped from 0.07% in 10/85-12/87 to between 0.02% and 0.03% in each of subsequent 3 year time intervals through 12/96 (data not shown; 1997-98 data not available).

- Nationally the percent of recruits testing HIV positive has dropped steadily since 1985 as shown below. The decline has been more notable among male recruits (from 0.14% in 1985-6 to 0.04% in 1997-98) than among female recruits (from 0.06 in 1985-6 to 0.03% in 1997-98)(data not shown).

Military recruits testing HIV positive
(US data, 1985-1998)

1985-87	0.14%
1988-90	0.10%
1991-93	0.06%
1994-96	0.04%
1997-98	0.04%

- HIV seropositivity in recruits from Seattle MSA (0.04%) and Tacoma MSA (0.06%) was two and three times, respectively that of the remainder of Washington State (0.02%) (data not shown).

- Washington State's seropositivity rate in female recruits (<0.01%) was less than one-fourth that of its male recruits (0.04%). Both sexes were lower than the national average (0.05% for women, 0.09% for men).

- Black men from Washington State had a considerably higher rate (0.23%) than White men (0.03%) , although both rates were lower than their national counterparts (0.29% and 0.04% respectively). The rate for Hispanic men from Washington (0.11%) was the same as the national rate.

- Of 4,498 Asian/Pacific Islanders (A/PI) tested in Washington, 2 (0.04%) were HIV positive. None of the 1,762 American Indian/Alaska Native (AI/AN) applicants tested positive. Nationally, 0.02% of A/PI and 0.04% of AI/AN tested positive, rates similar to or lower than the 0.04% seen in Whites (Data not given in Table 1.)

Table 1. HIV Prevalence among military recruit applicants, 10/85-12/98

Group	United States			Washington State			Seattle MSA[2]			Tacoma MSA[3]		
	HIV+	# tested	% HIV+	HIV+	# tested	% HIV+	HIV+	# tested	% HIV+	HIV+	# tested	% HIV+
All recruits[1]	4798	5789751	0.08	42	125042	0.03	16	37530	0.04	10	18148	0.06
All men[1]	4334	4845690	0.09	41	104782	0.04	16	31725	0.05	9	14507	0.06
All women[1]	464	944061	0.05	1	20260	0.00	0	5805	0.00	1	3641	0.03
All Whites	1467	4076342	0.04	23	106960	0.02	8	30918	0.03	2	13673	0.01
White men	1373	3493872	0.04	23	90443	0.03	8	26445	0.03	2	11163	0.02
White women	94	582470	0.02	0	16517	0.00	0	4473	0.00	0	2510	0.00
All Blacks	2762	1092106	0.25	12	6314	0.19	4	2546	0.16	6	2407	0.25
Black men	2427	828256	0.29	11	4723	0.23	4	1935	0.21	5	1739	0.29
Black women	335	263850	0.13	1	1591	0.06	0	611	0.00	1	668	0.15
All Hispanics	411	395267	0.10	4	4172	0.10	1	1081	0.09	2	636	0.31
Hispanic men	386	336948	0.11	4	3479	0.11	1	886	0.11	2	502	0.40
Hispanic women	25	58319	0.04	0	693	0.00	0	195	0.00	0	134	0.00
All 17-19 year olds	739	3211231	0.02	4	68166	0.01	1	19364	0.01	1	8677	0.01
17-19 yr. men	593	2696438	0.02	4	57510	0.01	1	16402	0.01	1	7120	0.01
17-19 yr. women	146	514793	0.03	0	10656	0.00	0	2962	0.00	0	1557	0.00
All 20-24 year olds	1782	1688004	0.11	17	34483	0.05	8	10728	0.07	4	5288	0.08
20-24 yr. men	1603	1407242	0.11	16	28599	0.06	8	9017	0.09	3	4147	0.07
20-24 yr. women	179	280762	0.06	1	5884	0.02	0	1711	0.00	1	1141	0.09
All 25-29 year olds	1315	520299	0.25	11	12096	0.09	4	4097	0.10	2	2207	0.09
25-29 yr. men	1233	431361	0.29	11	10026	0.11	4	3453	0.12	2	1688	0.12
25-29 yr. women	82	88938	0.09	0	2070	0.00	0	644	0.00	0	519	0.00
All 30+ year olds	962	370217	0.26	10	10297	0.10	3	3341	0.09	3	1976	0.15
30+ yr. men	905	310649	0.29	10	8647	0.12	3	2853	0.11	3	1552	0.19
30+ yr. women	57	59568	0.10	1650	1650	0.00	0	488	0.00	0	424	0.00

[1]Includes persons in racial categories not given in remainder of table

[2]Seattle MSA includes King, Snohomish, and Island counties

[3]Tacoma MSA is Pierce County

- Both locally and nationally, HIV seropositivity rates were lowest in 17-19 year old applicants and generally were highest in those over 30.

- Nationally, the ratio of seropositive men to women was highest in recruits age 25 and over (about 3:1 in both 25-29 and 30+ groups), and less in those 20-24 (about 2:1). Among 17-19 year olds, a higher proportion of females (0.03%) tested positive compared to males (0.02%).

HIV seroprevalence data from civilian military recruit applicants represent testing of a large number of persons from all areas of the U.S. over a long period of time. Military recruit results are limited by the lack of behavioral data, the relatively narrow age range tested, and because they likely underrepresent HIV prevalence in the general population due to self-selection bias. Nevertheless, these data define some of the major trends in the epidemic including the disproportionate impact of HIV on persons of color, the wide geographic variability in prevalence, and concern about HIV infection in young women.

❑ *Contributed by Sharon Hopkins DVM, MPH*

[1]Prevalence of HIV-1 antibody in civilian applicants for military service, October 1985 - December 1998. Department of Defense. Selected tables prepared by the Division of HIV/AIDS, Centers for Disease Control and Prevention, 1999.

HIV/AIDS Program Report: HIV counseling & testing model changes and public health HIV testing clinic closes

Public Health's Spring Street Clinic (formerly called the "AIDS Prevention Project" clinic) will close in May, 2000, but staff will continue at other sites to provide the same service levels, including anonymous and confidential HIV counseling & testing (C/T), STD evaluation, hepatitis services, Partner Contact and Referral Services (PCRS), and disease staging and referrals for persons newly diagnosed with HIV (the "One-on-One" program). Services will be delivered at other Public Health and field sites, using an outreach model first developed and implemented at a few sites beginning in 1989. This article describes the clinic's history, the model for outreach HIV C/T, the rationale for these changes, and results of that work from 1997 through 1999.

Clinic History: Public Health - Seattle & King County (PHSKC) first established an AIDS Assessment Clinic in 1983, initially in the downtown Public Safety Building, before HIV was known to be the cause of AIDS. This clinic moved to the Harborview STD Clinic in 1985, and then in 1986 to the corner of Summit and Seneca on First Hill where it was known as the AIDS Prevention Project. At that site, services were greatly expanded as part of the "Be-A-Star" research project funded by the U.S. Centers for Disease Control & Prevention (CDC). In 1992, the clinic moved to the corner of Blanchard and Fourth Avenues in downtown Seattle, sharing a facility with the Downtown Public Health Center. In 1998, the clinic moved to its current and final site at Spring Street on Capitol Hill.

Since 1986, Public Health staff have provided confidential and anonymous HIV counseling and testing and related services to over 25,000 individuals through this program, including 1,916 people who tested HIV positive at our site (through 1999). Since 1989 clinic staff have also been out-stationed at various venues frequented by persons at high risk for HIV, to make this service more accessible to people who might find it difficult to come to the clinic. Also, in 1990, with Ryan White Care Act funding, the clinic established the "One-on-One" program to provide anonymous and confidential comprehensive assessment and referral for persons newly diagnosed with HIV infection. And, in recent years clinic staff have added hepatitis screening, testing, and immunization services and STD evaluation for clients at risk of these conditions.

Client risk and clinical data obtained as a part of these services which have targeted people at highest risk of acquiring HIV have been summarized each quarter, repeatedly analyzed for multiple presentations and publications, and have provided a "window on the world" of persons at high-risk for HIV in Seattle and King County. These data were used in developing a prevention resource planning model, and have been deemed essential for use in the prevention planning processes used by the local prevention Planning Council.

The clinic and its clients have also participated in a number of on-site studies, resulting in publications on such topics as the oral manifestations of HIV, of the anal complications of human papilloma virus in men who have sex with men (MSM),[1] and of the human parvovirus, which have contributed to the understanding of these important problems. And, we've recruited large numbers of subjects for University of Washington studies including a number of HIVNet projects.

The Outreach Model: In effect after April of 2000, the outreach model will not reduce the current number of clinic staff nor the anonymous/confidential services that can be provided. We began providing HIV C/T at outreach sites in 1989 when staff brought these services to injection drug users (IDU) and their sexual partners at an office established in the Rainier Valley by POCAAN (the People of Color Against AIDS Network) and in downtown Seattle at SOS (Street Outreach Services), as a part of a three-year study funded by the National Institute on Drug Abuse (NIDA). Then,

in the early 90s we added weekend service sites, during late evening hours, at several coffee shops and bookstores on Capital Hill near gay bars. In recent years have been bringing HIV C/T, hepatitis services, and STD screening to gay pride events, and gay bath houses, in addition to the downtown and Stonewall needle exchange sites.

Although (after the closure) clinic staff will be officially housed at the main offices of the PHSKC HIV/AIDS Program (400 Yesler, Suite 300, Seattle, WA. 98104; 206-296-4649), our staff will continue to provide HIV C/T at many of the same field sites within King County, and some new ones – where they will spend most of their time. New sites (still being negotiated) will include other Public Health clinics as well as venues frequented by (or convenient to) persons at high risk for HIV. The clinic's One-on-One program will also operate at other Public Health clinics.

Clients needing HIV C/T, One-on-One, or other services will be asked to phone the Public Health HIV/STD Hotline, 206-205-STDS (7837) or the clinic phone number, 206-296-4848. These are the main numbers clients use to access our services. Trained interviewers will help clients determine which site and times would be most convenient for them.

Outreach sites for HIV C/T have been selected to meet a number of criteria, including: sites associated with active studies which have required clients to be offered HIV C/T, sites at venues frequented by persons at high risk for HIV (e.g., MSM, IDU, sex partners of these groups and of persons who carry HIV, and persons who exchange sex for money or other considerations), and sites which can provide adequate visual and sound separation from the surroundings, so that a client's confidentiality can be assured.

In some outreach settings we offer an abbreviated service model (an approximately 20 minute pre-test session) that has been piloted and found to be acceptable. Clients are given the option to provide their phone numbers if they would like to be contacted in the event of the need to reschedule follow-up appointments. All clients are given the option of receiving their test results either by telephoning our confidential results line, where results are given by trained counselors, or by scheduling an in-person follow-up appointment at one of our clinical service locations. However, persons selecting the phone results option are asked to commit to returning in person within one to two work days, should they test positive.

We have found that venues are most successful when the clinical services are coupled with some form of client outreach, which generally involves partner agency staff at the site. Thus, we welcome opportunities to collaborate with outreach workers from other agencies.

Our goals for outreach HIV C/T are to:

- Find people who need to learn that they are HIV-infected, so they can benefit from the new treatments;
- Bring individualized risk reduction counseling to populations with high risk of seroconversion; and
- Design services that will appeal to people who are at high risk for HIV infection and who have not previously sought HIV C/T.

Our strategies are to: 1) target populations at highest risk of being HIV-infected; 2) improve service accessibility by bringing them to the at-risk populations; and by 3) making the service accessible when high risk people may have the impulse to test.

At the host site, we will bring: 1) trained staff who can provide free, confidential and anonymous HIV C/T; 2) all materials and supplies necessary to provide the services; 3) all necessary medical records (which will be maintained off-site under high confidentiality protections); 4) practice liability coverage; and 5) we will leave our assigned space as we found it.

We will ask the host site to provide: 1) a minimum 6-month commitment to a stable weekly shift of at least 3 hours; 2) a private safe space where we can safely provide the services; 3) a designated contact person who is on-site during our services; 4) a written understanding of how to deal with clients who are waiting to see our staff person; 5) an agreement to post flyers that announce the availability of the service when our staff person is on-site; and 6) outreach and recruitment efforts to send high-risk clients to us.

We will consider a venue successful if 1) at least three-quarters (75%) of the people who test negative and almost all people (95%) who test positive receive their test results within 1 month of their test date, 2) at least 90% of

HIV/AIDS Program Outreach HIV C/T Results, 1997-1999	POCAAN	Bathhouse Sites	Needle Exchange Sites
TOTALS, 1997-99			
No. of clients	166	375	401
No. of visits	189	482	442
No. of visits per provider hour	1.63	1.50	1.67
% high risk clients	27%	100%	84%
% High risk not previously tested	22%	13%	6%
% testing HIV seropositive	42%	5%	1%
% HIV negative receiving results	85%	81%	62%
% HIV positive receiving results	100%	53%	78%
% HIV positive receiving follow-up	25%	28%	50%

positives return in person to see their counselor, 3) at least 1% test HIV positive, and 4) we achieve at least two of the following additional criteria:

- We provide at least 1.5 counseling sessions for each hour of health advisor time provided;
- Three-quarters (75%) of the people who use the service are at high risk for HIV infection (see above);
- At least a quarter (25%) of persons tested have not previously been tested, or have not been tested within the past 6 months;
- At least two of five (40%) of the people who test report at least one incident of unprotected anal intercourse or needle- or paraphernalia-sharing in the past 6 months.

At each venue we will collect, maintain, and evaluate the following data: 1) HIV risk information from the HIV labslip and data collection forms; 2) basic client demographics, including zip code; 3) approximate date and place of last HIV test; and 4) frequency of unprotected anal intercourse or needle- or paraphernalia-sharing, and number and gender of sex partners in the past three months.

Rationale for Clinic Closure: Possible closure of this clinic has been considered repeatedly over the past several years as the local demand for HIV C/T has decreased and as funding for this Clinic has diminished. Two sister programs have either left their space in the Clinic or will shortly do so, leaving us to pay the entire rent. In late 1999 the HIV Alternative Testing Study (HATS) Clinic moved to Harborview's new research facility, and in March, 2000 the Young Men's Survey ceased operations. Thus, the overhead for this Clinic is no longer supportable, and we have been unable to find a suitable new partner to share our space. Although the decision to close the Clinic falls on the heels of state initiative I-695 (the Motor Vehicle Excise Tax initiative), our decision to make this change was not based on this reduction of resources to Public Health.

As another important set of reasons, the transfer of PHSKC's HIV C/T and related services to other sites will enable more efficient and better targeted delivery of services to clients, by better enabling the HIV/AIDS Program to take services directly to clients' locales, and to bring expert models of HIV counseling and care to other clinical sites.

Our Outreach HIV C/T Experience to Date: The HIV/AIDS Program Clinic staff provided HIV C/T to five sites between 1997 and the end of 1999. These included two bathhouses for MSM (Club Z and Club Seattle), two needle exchange sites (Downtown and Stonewall) and the People of Color Against AIDS (POCAAN) site. In two of these sites (Club Z, a bathhouse for MSM, and the Downtown Needle Exchange storefront) services began in 1998 (data from earlier outreach HIV C/T activities are not presented here).

As shown in the table above, at least 1% of clients tested HIV seropositive at each of these sites. Assuming that a person always used the same identifier or anonymous code and was last seen at the outreach site, we altogether tested over 900 clients in these outreach settings, and 25 (2.7%) tested HIV se-

ropositive. Compared to our clinic site, however, where typically over 90% have returned for results, in outreach sites only 62-85% of people who tested seronegative received results and from 53-100% of the seropositives received their results, and only 25-50% of HIV positive persons actually saw a provider. These are problems that clearly to be addressed as we broaden this outreach program.

❑ *Contributed by Robert W. Wood MD, Carol Dunphy ARNP, Frank Chaffee, and staff of Public Health – Seattle & King County's HIV/AIDS Program*

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Adult AIDS Clinical Trials Unit Report: ACTU receives renewal of federal funding for 5 year period

We have good news to report with respect to our continued existence! We recently received the news that our unit, and the national research group that we are affiliated with (Adult AIDS Clinical Trials Group), received renewal of our federal funding for a five year period. The main funding for our program comes from these federal funds (YOUR tax dollars) via the National Institutes of Health (NIH). The purpose of the AIDS Clinical Trials Group and our unit is to perform research studies that will advance our understanding about the pathogenesis and treatment of HIV and its complications. The group conducts studies about antiretroviral therapy, methods to reconstitute the immune system, and prevention and treatment of opportunistic diseases that are associated with HIV infection. The AIDS Clinical Trials Group consists of 32 research clinics at academic centers throughout the United States, a statistical center at Harvard University, and a coordinating center in Maryland. We are the only Adult AIDS Clinical Trials Unit (ACTU) in the Pacific Northwest. The nearest Adult ACTU to us is in San Francisco. There are Adult ACTUs in 19 states and Puerto Rico.

On a local level, the University of Washington (UW) ACTU has existed since 1986 and has conducted over 100 HIV studies. Over two thousand persons have participated in studies done at the UW ACTU. The unit is staffed by highly skilled, dedicated physician's assistants, nurse practitioners, nurses, data staff, pharmacists, pharmacy and research assistants, and support staff. Faculty physicians from several departments are an integral part of the unit.

The UW ACTU is directed by Dr. Ann Collier, who is has particular expertise in antiretroviral therapy. Dr. Robert Coombs directs the UW Retrovirology Laboratory, which provides virological support to the UW ACTU. Dr. T. Mac Hooton is in charge of the opportunistic complications studies and Dr. Christina Marra is responsible for neurological studies. Dr. Jane Hitti is in charge of women's health studies. Dr. M. Juliana McElrath, aided by Drs. Dan Sabath and Uma Malhotra, provide immunological expertise and laboratory support to the ACTU. Dr. Jashvant Unadkat provides expertise in pharmacology. Drs. Margot Schwartz and Janine Maenza are faculty physicians at the UW ACTU. A cadre of other UW faculty with various expertise are consultants to the unit.

The UW ACTU is located at Harborview Medical Center in the new clinic building. Most studies are conducted there in outpatient volunteers. Selected studies require hospitalizations, which are either done at the UW General Clinical Research Center (UW Medical Center) or at Harborview Medical Center.

The vast majority of volunteers in UW ACTU studies are HIV-infected. However, we conduct occasional studies in HIV-negative volunteers; these are usually pharmacokinetic studies. The UW ACTU program is dependent upon the support of the HIV-infected community and their medical care providers. We appreciate the past support and referrals to our clinic and hope this support continues. We need those who know and work with HIV-infected persons to remind them about the importance of HIV-related treatment research and refer interested persons to the UW ACTU to get more information.

The UW ACTU has formal ties to the HIV-infected community. We have a Community Advisory Board (Group) that meets monthly. It advises the unit on issues and concerns about HIV treatment research and assists in outreach to the community. Anyone interested in attending is welcome. Please call the UW ACTU at 731-3184 for information about meeting dates, time and location. The UW ACTU also has an active outreach program to inform the HIV-affected community about us and our studies. The UW ACTU also collaborates with POCAAN to provide information about HIV research and the UW ACTU to communities of color.

Participants are being sought for several studies. Screening tests, study medications, and laboratory and clinical monitoring that are performed as part of our studies are free of charge for potential participants and study enrollees. The unit does not assume the role

UNIVERSITY OF WASHINGTON AIDS CLINICAL TRIALS UNIT

HARBORVIEW MEDICAL CENTER, 2 WEST CLINIC, 325 9TH AVENUE, BOX 359929, SEATTLE, WA 98104 -- (206)731-3184

ANTIRETROVIRAL / IMMUNOLOGICAL STUDIES OPEN FOR ENROLLMENT – WINTER 2000

TOPIC	TREATMENTS	ELIGIBILITY	LENGTH	MISCELLANEOUS	STUDY #
Once a day dosing of ritonavir and saquinavir vs efavirenz + 2 NRTIs	• Saquinavir + ritonavir + 2 NRTIs **OR** • Efavirenz + 2 NRTIs	• CD4 ≥100 cells/mm^3 • Viral load ≥5000 • No previous antiretrovirals	48 weeks	• $20 reimbursement per visit • $25 for each DEXA abdominal scan for substudy	072
Safety and anti-HIV effect of a new drug, AMD-3100 (fusion inhibitor)	• AMD-3100 is given intravenously continuously for 10 days	• 18-55 years of age • Medically stable & all lab tests within normal limits. • No changes to antiretrovirals for >4 weeks prior to entry, **OR** not on antiretrovirals • Viral load > 5,000 / CD4 >50	15 weeks	• 12 day hospitalization, reimbursement of $100/day (maximum total $1,200, paid ***after study completion***)	066
Effect of GM-CSF	• GM-CSF or placebo for 16 wks • Open-label drug for 32 wks	• Currently taking potent antiretroviral therapy	52 weeks	• Drug given by injection under skin	5041
Drug levels of amprenavir, efavirenz, and another PI	• APV and EFV for 2 weeks • IDV, NFV, RTV, or SQV added for 2 weeks	• **HIV negative** • Taking no medications • Within 20% of ideal body weight	6-7 weeks	• $500 reimbursement for 2 12-hour hospitalizations	5043
Protease inhibitor levels in tissues. Any CD4.	None	• Study of persons planning to start a protease inhibitor.	8 weeks	• Blood draws and genital fluid collections done at entry, wk 4, wk 8. • Four spinal taps (lumbar puncture): $100 reimbursement for first two, $125 each for third and fourth (total $450).	032
Hearing Loss with AZT or ddI	None	• Starting AZT and/or ddI (with other antivirals). CD4 counts >200 cells/mm^3.	32 weeks	• $20 reimbursed for each of 3 hearing tests. • Blood draws & urine sample: entry & weeks 16 & 32.	047
Effect of contraceptive medications on AZT	None	• Any CD4 or viral load • Must be on AZT, and • Starting Ortho-Novum 1/35 or Depoprovera	6 weeks	• ***Women only.*** • Four 10-hour visits; $75 per visit	317

of primary care provider for study participants, but coordinates care with each patient's primary care provider. Physicians, their staff, or potential enrollees can call Karen Novak, Margot Perrin, or Steve Wroblewski at 731-3184 for additional information or appointments.

ACTU Web Page:
http://depts.u.washington.edu/~actu
ACTU e-mail: actu@u.washington.edu

❑ *Contributed by Ann Collier MD*

UNIVERSITY OF WASHINGTON AIDS CLINICAL TRIALS UNIT

OPPORTUNISTIC DISEASE & OTHER CONDITION STUDIES OPEN FOR ENROLLMENT – WINTER 2000

CONDITION	TREATMENTS	LENGTH	DESCRIPTION	STUDY #
AIDS Dementia Complex	CPI-1189 vs. placebo	10 or 22 weeks	• Study of the safety and effectiveness of the experimental drug CPI-1189 in treating AIDS Dementia Complex. • On stable ARV regimen (or no regimen) for 6 weeks prior to entry. • 8 visits total, each about 1 hour, plus additional time for special optional testing (neuropsychological tests and lumbar punctures). • $20 reimbursement for each neuropsychological exam (4in all), and $100 for each optional lumbar puncture (3 in all).	103A
Peripheral neuropathy	Lamotrigine (Lamictal®) vs. placebo.	19 weeks	• Tests safety and effectiveness of lamotrigine in treating peripheral neuropathy pain. • No pain medication, / **OR** >4 weeks of pain meds. • No ddI, ddC, or d4T for 8 weeks prior to entry, or currently on for >8 weeks. • 7 study visits, $20 reimbursement per visit.	086
Thrush in past 2 years CD4 count <150	Fluconazole	24 months	• Open label study of fluconazole in two long term management strategies for thrush: chronic suppressive vs episodic therapy.	323

Screening tests, study medications, and laboratory and clinical monitoring that are part of our studies are free of charge.

Key to Terms:

3TC:	**Epivir (lamivudine)**	**ddC**	**Hivid (zalcitabine)**
ABC:	**Ziagen (abacavir)**	**HAART:**	**Highly active antiretroviral therapy**
ARV:	**Antiretroviral**	**NRTI:**	**Nucleoside reverse transcriptase inhibitor**
AZT:	**Retrovir (zidovudine)**	**NNRTI:**	**Non-nucleoside reverse transcriptase inhibitor**
ddI:	**Videx (didanosine)**	**PI:**	**Protease inhibitor**
d4T:	**Zerit (stavudine)**	**GM-CSF:**	**Granulocyte macrophage colony stimulation factor**
APV:	**Egenerase (amprenavir)**	**IDV:**	**Crixivan (indinavir)**
EFV:	**Sustiva (efavirenz)**	**NFV:**	**Viracept (nelfinavir)**
RTV:	**Norvir (ritonavir)**	**SQV:**	**Invirase (saquinavir)**

Physicians or potential participants can call Karen, Margot, or Steve at (206) 731-3184 for information or appointments.

ACTU Web Page: http://depts.washington.edu/actu/ ***ACTU Email: actu@u.washington.edu***

Pediatric AIDS Clinical Trials Unit Report: What effects do antiretroviral agents have on the developing fetus?

A major goal of clinical trials by the Pediatric AIDS Clinical Trials Group is the interruption of transmission of HIV-1 from an infected pregnant women to her infant. To date, several trials have been very successful in reducing the rate of transmission. As a consequence, the number of newborn infants infected with HIV-1 in the United States has decreased substantially with the institution of standard antiretroviral treatment regimens for HIV-1 infected pregnant women.

Currently, between 90% to nearly 100% of infants born to HIV-1 infected women do not become infected when viral replication in the mother is suppressed by antiretrovirals and/or the infant receives antiretroviral prophylaxis to inhibit HIV from infecting the newborn cells. Due to the potential adverse effects of nucleoside analogues, the long-term safety of zidovudine in the developing fetus has been the focus of PACTG 219. Recently, after reports suggesting that peripartum combination antiretroviral therapy was associated with an increased risk of preterm deliveries, and that antepartum nucleoside analogues were associated with symptoms of mitochondrial disorders in infants, additional cohorts have been examined.

PACTG 367 is an ongoing retrospective and prospective abstraction of prenatal records of HIV-1-infected women delivering between January 1998 and October 1999 at 32 sites participating in the Pediatric AIDS Clinical Trials Group (PACTG). Among 945 women with known pregnancy outcome after more than 20 weeks' gestation, antepartum protease inhibitor use did not appear to be associated with increased rates of adverse outcomes. In the study 13% women received no or unknown antiretroviral therapy, 19% ZDV only, 20% ZDV/3TC, 8% combination therapy without protease inhibitor (PI), and 40% combination therapies with PI during pregnancy. The proportion of women who received antiretrovirals increased each trimester. Preterm births <37 or <32 weeks' gestation and low birth weight <2500 or <1500 grams were not increased, at 37%, 2%, 19%, and 3%, respectively. There were 6 stillbirths and 41 structural anomalies, most of which were of minor significance (e.g., polydactylism). HIV-1 transmission rates according to maternal antiretroviral therapy were: none/unknown: 26%; ZDV: 7.8%; ZDV/3TC: 1.1%, multiagent/no PI: 3.4%; multiagent with PI: 1.1%, with overlapping 95% confidence intervals in the latter three groups.

To evaluate the possibility of mitochondrial toxicity related to antiretroviral prophylaxis therapy for interrupting perinatal HIV-1 transmission, the outcome of uninfected living children in the Women and Infants Transmission Study (WITS) and the infants and children enrolled in PACTG and Centers for Disease Control (CDC) cohorts have been reviewed and no child in the 3 cohorts has emerged with classic findings of mitochondrial dysfunction.

Among 1189 children in the WITS cohort, none was found with classic mitochondria dysfunction, characterized by myopathy, cardiomyopathy, pancytopenia, retinitis pigmentosa, myocarditis, pericarditis, renal failure, or persistent metabolic acidosis. Eighteen percent had nonspecific symptoms possibly consistent with mitochondrial defects, failure to thrive, short stature, microcephaly, neurologic findings (hypotonia, hypertonia, ataxia, seizure disorder [febrile or afebrile], autism, developmental delay), rhythm disturbances, anemia, neutropenia, blindness, oculomotor defects, and/or deafness.

The symptoms in these 123 children were classified as unrelated to mitochondrial toxicity (n= 92), unlikely to be due to mitochondrial toxicity (n=27), mitochondrial toxicity possible (n=2), mitochondrial toxicity likely (n=0), and insufficient information to evaluate (n=1). Infants were classified without knowledge as to whether the infant had been exposed to antiretrovirals. About half of the infants were exposed to antiretrovirals (mostly zidovudine), including two-thirds classified as possibly having mitochondrial toxicity. The one child who could not be classified had hypotonia noted when about 3 years old and has been lost to follow-up.

PACTG treatment trials will continue to prospectively monitor and evaluate pregnant women and their infants for potential adverse events associated with the use of antiretroviral regimens for the prevention of perinatal transmission of HIV. Evaluation of antiretroviral-exposed infants will include a battery of tests to specifically evaluate mitochondrial toxicity, including evaluation of lactic acidosis and muscle biopsies for symptomatic infants and children. Potential new diagnostic strategies, such as the use of cord blood to evaluate infants for mitochondrial toxicity, are being developed to screen infants for mitochondrial dysfunction.

❑ *Contributed by Lisa Frenkel MD*

Main Requirements	Study Drug or Topic	Study Overview
Pediatric Antiretrovirals:		
≥16 weeks antiretroviral therapy, ages 4 months-17 years	**d4T/evirapine/ritonavir vs. d4T/3TC/nelfinavir (TID) vs. d4T/nevirapine/nelfinavir (TID) vs.d4T/3TC/ nevirapine/nelfinavir** (ACTG 377) (Closed to accrual)	A Phase I/II randomized, multicenter protocol comparing four antiretroviral regimens containing combinations of protease inhibitors, NRTIs and an NNRTI in mildly symptomatic HIV-1-infected children aged 4 months to 17 years of age. The purpose of this study is to evaluate the ability of these regimens to delay disease progression.
Cohort 1: ≤ 16 years of age and able to swallow pills Cohort 2: ≥ 3 month to ≤ 8 years (suspension	**DMP-266 Nelfinavir** (ACTG 382) (Cohort 1 accrued) (Cohort 2 temporarily closed to accrual)	Phase 1, open-label pharmacokinetic study of a new non-nucleoside reverse transcriptase inhibitor given once daily in combination with nelfinavir. Concomitant use of nucleoside reverse transcriptase inhibitors are required, but are not supplied through this protocol.
Children aged 3-16 years of age and able to swallow capsules. Must be naïve to at least one of the following: stavudine, zidovudine, or ddI	**Saquinavir soft-gel plus 2 NRTI's of choice Vs. Saquinavir soft-gel plus nelfinavir plus one or two NRTI's of choice** (ACTG 397) (Closed to accrual pending amendment)	This is a Phase I study to evaluate the safety and tolerance of 2 saquinavir soft-gel containing treatment arms. Children must have a viral load >10,000 at entry to be eligible. Intensive pharmacokinetics will be obtained from a subset of children randomizing to the saquinavir soft-gel plus nelfinavir arm of the study. Because saquinavir soft gel is not available as a liquid formulation, children must be able to swallow capsules.
Perinatal Treatment Studies:		
Pregnant woman unable to tolerate zidovudine or choosing not to take zidovudine	**Stavudine (d4T)** (ACTG 332)	This is a Phase 1 pharmacokinetic study of stavudine given to pregnant women during pregnancy, labor and delivery and to their newborns for 6 weeks. Newborns will either receive stavudine or zidovudine. The objective is to define the appropriate stavudine dose for the pregnant woman and obtain ascertain the safety of stavudine for both the pregnant woman and newborn.
Pregnant HIV-infected women who have not received nevirapine	**Nevirapine** (ACTG 316)	Pregnant women infected with HIV and who are naïve to nevirapine are eligible for this study. During labor and delivery women will be given a single dose of nevirapine or placebo. Newborn infants will receive a single dose of nevirapine or placebo (same as mother) between 48-72 hours of life. Women may continue zidovudine or other antiretroviral medications, except nevirapine, through pregnancy. The goal of the study is to determine if nevirapine administered at the time of delivery and to the newborn will further decrease maternal-infant HIV transmission.
Pregnant HIV-infected women	**Saquinavir-SGC, lamivudine, zidovudine** (ACTG 386)	This is a Phase I study of the safety and correct dose of saquinavir-SGC given in combination with zidovudine and lamivudine during pregnancy and labor and delivery. Women may begin therapy at 13 weeks gestation and continue until 6 weeks postpartum.

Newborn infants born to HIV-infected pregnant women	**Increased calorie formula** (ACTG 247)	This is a randomized, double-blind, controlled study of an increased caloric density formula and its effect on growth and nutritional status of HIV-infected children. All infants born to HIV-infected women are eligible for enrollment, however infants found to be uninfected will be discontinued from the study.
Pregnant HIV-infected women	**Nelfinavir, lamivudine, zidovudine** (ACTG 353)	This is Phase I study of the safety, tolerance and pharmacokinetics of nelfinavir given with zidovudine and lamivudine to HIV-1 infected women and their newborns. Women may have had prior nelfinavir therapy. Women are enrolled between 14-32 weeks gestation.
Newborn infants born to HIV-infected pregnant women	**GP 120 vaccine** (Study to re-open to accrual with amendment)	This Phase I study of the safety and immunogenicity of ALVA-MN120TMG vaccine given to infants born to HIV-infected women within 72 hours of birth. Infants receive additional vaccinations at 4,8, and 12 weeks of life; 18 infants receive vaccine, 6 receive placebo.
Opportunistic Infections:		
HIV infected children and adolescents ≥2 years ≤21 years with CD4 % as follows: >2 and <6 years CD4% >25% >6 and <21years CD4% >20	**No study drugs. Purpose to stop prophylaxis** (P1008)	This is a study to evaluate the safety of stopping PCP and MAC prophylaxis in children whose CD4% has increased following institution of effective antiretroviral therapy. It is an observational study of the rate of opportunistic events in children who have discontinued prophylactic medications.
Natural History Studies:		
HIV-infected, severely immunocompromised (CD4% < 10%)children aged 4-17 years initiating open-label HAART therapy	**Effects of HAART on immune reconstitution** (P1006)	P1006 is a study designed to measure how well the immune system recovers once aggressive antiretroviral medications are started. No antiretroviral medications will be provided as part of this study. Children will receive hepatitis A and tetanus vaccines as part of the study; response to these vaccines will be used as a measure of immune function.
HIV-negative, non-exposed, normal children aged 0-18 years	**Purpose to obtain normal ranges of lymphocyte subsets in children.** (P1009)	P 1009 is an observational, cross-sectional study to obtain the normal range of lymphocyte subsets in children. Study involves a one time blood draw from children undergoing elective surgeries or having blood taken for other non-illness associated purposes.
HIV-infected young persons, >8years up to 22 years of age, who did not acquire infection perinatally	**Effects of HAART on immune reconstitution and viral dynamics.** (ACTG 381)	This is a non-randomized, observational study to define the immune reconstitution that occurs following institution of Highly Active Antiretroviral Therapy (HAART) in the recently infected adolescent. The study objective is to determine if, controlling for viral load at baseline, there is a positive correlation between baseline immunologic status and the virologic and immunologic response to HAART at 1,2,and 3 years after initiation of HAART.
Infants of women who were enrolled in treatment trials during pregnancy; infants and children enrolled in ACTG treatment or vaccine trials	**Observational study to look for long term outcomes** (ACTG 219)	Open to all infants and children currently or previously participating in HIV treatment protocols, including infants born to women who participated in a trial during pregnancy. The purpose of the study is to determine late effects of HIV therapies and HIV infection in children.
Pending Perinatal Treatment Studies:		
Pregnant HIV-infected women and their newborn infants	**No treatment** (ACTG 367)	This is a chart abstraction study to capture data about the clinical management of HIV infection in pregnant HIV-1 women and their infants. This information will be useful in the design of clinical trials to treat HIV-l in pregnant women and to prevent transmission of HIV-1 to infants.

For further information contact:
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AIDS Vaccine Evaluation Unit Report

Since 1988, the AVEU has enrolled over 800 Seattle-area volunteers in safety studies of experimental vaccines against HIV. The AVEU has focused on ongoing studies during the last quarter of 1999. Protocols which are fully enrolled and active include:

- Protocol 202, a Phase II, canarypox (ALVAC vCP205) and gp120 combination
- Protocol 027, testing mucosal immunization with ALVAC vCP205
- Protocol 036, testing gp120 vaccines at low doses with QS-21 adjuvant
- Protocol 032, with a new p24 subunit, given with ALVAC vCP205 and gp120
- Protocol 034A, evaluating two canarypox vaccines, ALVAC vCP205 and ALVAC vCP1452 in a head-to-head trial
- Protocol 031, testing a DNA vaccine, which was recently amended to add a canarypox boost.

Through our long term follow-up protocol, we contact former volunteers once a year by phone or mail for seven years after they first join a study, to obtain a health update for long term safety data. Long term safety with the vaccines to date has been excellent.

This spring, Protocol 038, also known as the "Memory" Protocol, will involve volunteers who have already participated in selected HIV vaccine studies. These volunteers will be given a single booster of a canarypox-based HIV vaccine, to evaluate the memory immune response. This is a brief study lasting three months. A few new volunteers will also be needed, for comparison with previously vaccinated volunteers.

Protocol anticipated in the summer of 2000 will include Protocol 203, a Phase II, canarypox and envelope subunit study involving healthy, HIV-1 uninfected volunteers at low or high risk for HIV infection. This will be a large study involving 450 people in the US, including 100 from the Seattle area.

If you would be interested in an small group inservice to update your group on the HIV vaccine research effort, or to discuss ways in which your group might be able to help with community recruitment for the next large vaccine trial, please contact David Richart at (206)667-2376. We look forward to meeting with you.

❑ *Contributed by Marnie Elizaga MD*

AIDS Vaccine Evaluation Unit

http://depts.washington.edu/vaccine

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Volunteers Needed

Must be 18-60 years of age, healthy, HIV-negative, and available for 18 months to two years. Please call (206)667-2300 for more information.